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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,928	02/10/2004	Wing K. Cheung	JJPR-0048(ORT-1223)	1406
27777	7590	11/28/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/775,928	Applicant(s) CHEUNG ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over Woog et al (U.S. Patent No. 5,503,827) in view of Woog et al (U.S. Patent No. 4,992,419). Woog et al '827 teaches an aqueous pharmaceutical preparation comprising erythropoietin, a pH buffering agent (i.e. sodium phosphate monobasic/sodium phosphate dibasic), Tween 20 (i.e. polysorbate 20), a stabilizing amount of glycine, and sodium chloride (i.e. a tonicity agent). Tween 20 concentration is about 0.1 g/l, and glycine concentration is about 1.5 g/l. The composition does not contain any urea, human blood product such as serum albumin, or calcium chloride. See Example 1, third column of the table, where the dash in the row "calcium chloride x 2H<sub>2</sub>O" is interpreted as meaning that no calcium chloride is present. See also column 9, lines 5-12, for the function of glycine in the preparation. Woog et al '827 teaches the presence of a sodium phosphate monobasic/sodium phosphate dibasic buffer, and in the example teaches 38.4 grams of the monobasic and 350 grams of the dibasic in 70 l of water, i.e. a combined concentration of about 32 mM. Because of Applicants' use of the claim terminology "about" in the pH buffering agent concentration range, Woog et al '827's buffer concentration is deemed to anticipate Applicants' claimed range. Note that use of the term "about" permits some tolerance in a claim. See *In re Ayers*, 69 USPQ 109 (CCPA 1946) and *In re Erickson*, 145 USPQ 207 (CCPA 1965). To the extent that the buffer concentration in Woog et al '827's example does not anticipate Applicants' pH buffering agent concentration range, Woog et al '827 teaches in general buffer concentrations of about 1 - 100 mmol/l (see column 8, lines 25-31). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all

Art Unit: 1654

operable and optimal buffer concentrations within the disclosed ranges of Woog et al '827 because concentration is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts, and which Woog et al '827 teaches must be chosen for pharmaceutical use. In Example 1, third column of the table, Woog et al '827 teaches an erythropoietin composition comprising Tween 20 rather than Tween 80. Woog et al '827 do not teach the function of the Tween 20 in the composition. Woog et al '419 teaches erythropoietin compositions in which a non-ionic wetting agent, preferably Tween 20 or 80, preferably in amounts of 0.1 to 0.5 g/liter, is included to prevent adhesion of erythropoietin onto ampoule walls and syringes. See column 2, line 64 - column 3, line 9. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to substitute Tween 80 for Tween 20 in the erythropoietin composition of Woog et al '827 because Woog et al '419 teach them to be functionally equivalent in prevent adhesion of erythropoietin onto apparatus walls, and because the substitution of one known functional equivalent for another is prima facie obvious.

3. Applicant's arguments filed November 6, 2006 have been fully considered but they are not persuasive.

Applicants did not address in their Remarks the obviousness rejection based upon Woog et al (U.S. Patent No. 5,503,827) in view of Woog et al (U.S. Patent No. 4,992,419) set forth in the previous Office action and essentially repeated above. The examiner does not agree that determining concentrations of components in a pharmaceutical composition is beyond the ability of one of ordinary skill in the art. See, e.g., Woog et al '827 at column 3, lines 59-61; and MPEP 2144.05(II)(A). Further, Woog et al '827 and Woog et al '419 do teach relative amounts of the

Art Unit: 1654

components present in their compositions, e.g., in the example and at column 8, lines 25-31, of Woog et al '827, and at column 3, line 2, of Woog et al '419. Woog et al '827 does not teach away from Applicants' claimed concentrations because Applicants' claimed concentrations are embraced within the disclosure of Woog et al '827. It is noted that Applicants' claims also permit varying relative amounts of the claimed components. Applicants' claimed compositions do not appear to exhibit any properties or functions not possessed by the compositions of Woog et al '827 or Woog et al '419.

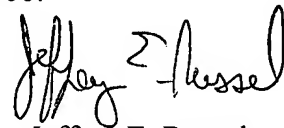
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel  
November 18, 2006